



Attorney's Docket No.: 10274-006002 / D011 CIP2

16408/#5  
1/7/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Wallner et al.

Art Unit : Unknown

Serial No. : 09/730,465

Examiner : Unknown

Filed : December 5, 2000

Title : METHOD OF PROPHYLAXIS OR TREATMENT OF ANTIGEN PRESENTING  
CELL DRIVEN SKIN CONDITIONS USING INHIBITORS OF THE CD2/LFA-3  
INTERACTION

Commissioner for Patents  
Washington, D.C. 20231

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INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the attached form PTO-1449.

Under 35 USC §120, this application relies on the earlier filing date of application serial number 08/466,465, filed on June 6, 1996. References AA-ATTTT were submitted to and/or cited by the Office in the prior application and, therefore, are not provided in this application. References AVVVV-AIIII are submitted herewith.

This statement is not to be interpreted as a representation that the cited references are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any reference herein be construed per se as a representation that such reference is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited references.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

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Roberta L. Hahn

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Serial No. : 09/730,465  
Filed : December 5, 2000  
Page : 2

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This statement is being filed within three months of the filing date of the application or before the receipt of a first Office action on the merits. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: October 24, 2001

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Sheet 1 of 6

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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 10274-006002	Application No. 09/730,465
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Wallner et al.	
		Filing Date December 5, 2000	Group Art Unit

### U.S. Patent Documents

Examiner Initial	Desig. ID	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	08/459,350		Wallner et al.			June 2, 1995
	AB	4,956,281	Sept. 9, 1990	Wallner et al.			
	AC	5,225,538	July 6, 1993	Capon et al.			
	AD	5,547,853	Aug. 20, 1996	Wallner et al.			

### Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AE	EP O 280 578	02/1988	EPO				
	AF	WO 90/02181	03/1990	WIPO				
	AG	WO 90/08187	07/1990	WIPO				

### Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AH	(Editors) (1990) "Adhesion Molecules in Diagnosis and Treatment of Inflammatory Diseases" <i>The Lancet</i> 336:1351-1352
	AI	Abraham et al. (1990) "Interactions Between Lymphocytes and Dermal Fibroblasts: An <i>In Vitro</i> Model of Cutaneous Lymphocyte Trafficking" <i>Exp. Cell. Res.</i> 190:118-126
	AJ	Abraham et al. (1991) "Expression and Function of Surface Antigens on Scleroderma Fibroblasts" <i>Arthritis and Rheumatism</i> 34(9):1164-1172
	AK	Altman et al. (1990) "Transfection of Genes For Cell Surface Products Involved in Antigen Presentation-Applications to the Understanding of Autoimmunity" <i>Autoimmunity</i> 7:213-220
	AL	Baadsgaard et al. (1989) "Psoriatic Epidermal Cells Demonstrate Increased Numbers and Function of Non-Langerhans Antigen-presenting Cells" <i>J. Invest. Dermatol.</i> 92:190-195;
	AM	Baadsgaard, O. et al. <i>J. Invest. Dermat.</i> 92(2): 190-195 (1989)
	AN	Barbosa et al. (1986) "Gene Mapping And Somatic Cell Hybrid Analysis Of The Role Of Human Lymphocyte Function-Associated Antigen-3 (LFA-3) In CTL-Target Cell Interactions: <i>J. Immunol.</i> 136:3085-3091;
	AO	Bierer and Burakoff (1988) "T Cell Adhesion Molecules" <i>FASEB J.</i> 2:2584-2590;
	AP	Bierer et al. (1988) "Expression of the T-Cell Surface Molecule CD2 and an Epitope-Loss CD2 Mutant to Define the Role of Lymphocyte Function-Associated Antigen 3 (LFA-3) in T-Cell Activation" <i>Proc. Natl. Acad. Sci. USA</i> 85:1194-1198
	AQ	Bierer et al. (1989) "A Monoclonal Antibody to LFA-3, the CD2 Ligand, Specifically Immobilizes Major Histocompatibility Complex Proteins" <i>Eur. J. Immunol.</i> 19:661-665;

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Sheet 2 of 6

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### Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Design ID	Document
	AR	Bockenstedt et al. (1988) "The CD2 Ligand LFA-3 Activates T Cells But Depends On The Expression And Function Of The Antigen Receptor" J. Immunol. 141:1904-1911;
	AS	Bromberg et al. (1991) "Anti-CD2 Monoclonal Antibodies Alter Cell-Mediated Immunity In Vivo" Transplantation 51:219-225;
	AT	Brown et al. (1987) "T2.2 Characterization Of CD2 Epitopes By Western Blotting: in Leukocyte Typing III, A.J. McMichael (ed.) Oxford, England: Oxford University Press, 110-112;
	AU	Brown et al. (1989) "The CD2 Antigen Associates With The T-Cell Antigen Receptor CD3 Antigen Complex On The Surface Of Human T Lymphocytes" Nature 339: 551-553;
	AV	Chang et al. (1992) "T-Cell Activation Is Potentiated by Cytokines Released by Lesional Psoriatic, but not Normal, Epidermis" Arch. Dermatol. 128:1478
	AW	Chin, Y.H. et al. J. Invest. Dermatol. 93(2) Supplemental: 82S-87S (1989)
	AX	Clayton et al. (1987) "Murine and Human T11 (CD2) cDNA Sequences Suggest A Common Signal Transduction Mechanism" Eur. J. Immunol. 17: 1367-1370;
	AY	Conti and Cosimi (1990) "Effect of Monoclonal Antibodies on Primate Allograft Rejection" Crit. Rev. Immunol. 10(2): 113-130
	AZ	Cooper (1990) "Immunoregulation in the Skin" Current Problems in Dermatology 19:69-80;
	AAA	Cooper (1992) "Skin-infiltrating Lymphocytes in Normal and Disordered Skin: Activation Signals and Functional Roles in Psoriasis and Mycosis Fungoides-type Cutaneous T Cell Lymphoma" J. Dermatol. 19:731-737;
	ABB	Cooper et al. (1985) "Effects of ultraviolet radiation on human epidermal cell alloantigen presentation; initial depression of langerhans cell-dependent function is followed by appearance of T6-Dn+ cells that enhance epidermal alloantigen presentation: J. Immunol. 134: 129-137;
	ACC	Cunningham and Harris (1992) "Antibody engineering - how to be human: TIBTECH 10;
	ADD	Curtis and Barnes (1992) "The Nature of Science" in Biology, 5 <sup>th</sup> ed. (Worth Publishers, Inc.): 14-15;
	AEE	Denning et al. (1987) "Monoclonal Antibodies to CD2 and Lymphocyte Function-Associated Antigen 3 Inhibit Human Thymic Epithelial Cell-Dependent Mature Thymocyte Activation: J. Immunol. 139: 2573-2578;
	AFF	Denning et al. (1988) "Purified Lymphocyte Function-Associated Antigen-3 (LFA-3) Activates Human Thymocytes Via The CD2 Pathway" J. Immunol. 141: 2980-2985;
	AGG	Dustin et al. (1987) "Purified Lymphocyte Function-Associated Antigen 3 Binds to CD2 And Mediates T Lymphocyte Adhesion" J. Exp. Med. 165: 677-692;
	AHH	Dustin et al. (1987) "T Cell Activation By LFA-3 and CD2 Antibodies" FASEB J. 45: A1239 (Abstract No. 5484);
	AII	Gonzalez-Ramos et al. (1992) "APC-Targeted Immunointervention in Psoriasis: Blockade of LFA-3-CD2 and ICAM 1-LFA1 Ligand Pairing Blocks Autoreactivity to Lesional Epidermis" Clinical Research 40(2):500A;
	AJJ	Harris and Emery (1993) "Therapeutic antibodies - the coming of age" TIBTECH 11: 42-44;
	AKK	Haynes, B.F. et al. Arthritis and Rheum. 31 (8): 947-955 (1988)
	ALL	Howard et al. (1981) "A human T lymphocyte differentiation marker defined by monoclonal antibodies that block E-rosette formation: J. Immunol. 126:2117-2122;

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**Other Documents (include Author, Title, Date, and Place of Publication)**

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	AMM	Hughes et al. (1990) "Endothelial Cells Augment T Cell Interleukin 2 production by a Contact-Dependent Mechanism involving CD2/LFA-3 Interaction" J. Exp. Med. 171:1453-1467;
	ANN	Hughes et al. (1990) "The Endothelial Cell As A Regulator Of T-Cell Function" Immunol. Rev. 117, 85-102.
	AOO	Kaplan et al. (1987) "Distribution and Turnover of Langerhans Cells During Delayed Immune Responses in Human Skin" J. Exp. Med. 165:763-776;
	APP	Koyasu et al. (1990), "Role of Interaction Of CD2 Molecules With Lymphocyte Function-Associated Antigen 3 In T-Cell Recognition of Nominal Antigen" Proc. Natl. Acad. Sci. USA 87: 2603-2607;
	AQQ	Krensky (1990) "The Human Cytolytic T Lymphocyte Response to Transplantation Antigens" Pediatric Res. 19: 1231-1234;
	ARR	Krensky et al. (1983) "The Functional Significance, Distribution, and Structure of LFA-1, LFA-2, and LFA-3: Cell Surface Antigens Associated With CTL-Target Interactions" J. Immunol. 131:611-616;
	ASS	Krensky et al. (1984) "Human Lymphocyte Function Associated Antigens" Surv. Immunol. Res. 3:39-44;
	ATT	Larson and Springer (1990) "Structure and function of leukocyte integrins" Immunol. Revs. 114:181-217;
	AUU	Le et al. (1987) "Anti-LFA-3 Monoclonal Antibody Induced Interleukin 1 (IL 3) Release by Thymic Epithelial (TE) Cells and Monocytes" FASEB J. 46(3):447 Abstract 761;
	AVV	Le et al. (1990) "Ligan Binding to the LFA-3 Cell Adhesion Molecule Induces IL-1 Production By Human Thymic Epithelial Cells" J. Immunol. 144:4541-4547;
	AWW	Makgoba et al. (1989) "The CDA2-LFA-3 And LFA-1-ICAM Pathways: Relevance to T-Cell Recognition" Immunol. Today 10:417-422;
	AXX	Makgoba, M. et al. Immunol. Today 10 (12): 417-422 (1989)
	AYY	Martz and Gromkowski (1985) "Lymphocyte Function-Associated Antigens: Regulation of Lymphocyte Adhesions In Vitro and immunity In Vivo" Adv. Exp. Med.Biol. 184:291-310;
	AZZ	Matis (1990) "The molecular basis of T-cell specificity" Ann. Rev. Immunol. 8:65-82;
	AAAA	Meuer et al. (1984) "An Alternative Pathway of T Cell Activation: A Functional Role for the 50 kd T11 Sheep Erythrocyte Receptor Protein" Cell 36:897-906;
	ABBB	Meuer et al. (1984) "The human T-cell receptor" Ann. Rev. Immunol. 2:23-50;
	ACCC	Meuer et al. (1989) "The Alternative Pathway of T Cell Activation: Biology, Pathophysiology, and Perspectives for Immunopharmacology" Clin. Immunol. Immunopath. 50:S133-S138;
	ADDD	Miller (1993) "Specific Interactin of Lymphocyte Function-associated Antigen 3 with CD2 Can Inhibit T Cell Responses" J. Exp. Med. 178:211-222;
	AEEE	Moingeon et al. (1989) "The Structural Biology of CD2" Immunol. Rev. 111:111-144;
	AFFF	Moingeon et al. (1991) "Complementary Roles for CD2 and LFA-1 Adhesion Pathways During T Cell Activation" Eur. J. Immunol. 21:605-610;
	AGGG	Nathan et al. (1986) "Local and Systemic Effects of Intradermal Recombinant Interferon-γ in Patients with Lepromatous Leprosy" New Eng. J. Med. 315(1):6-15;

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Substitute Disclosure Form (PTO-1449)



Sheet 4 of 6

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**Other Documents (include Author, Title, Date, and Place of Publication)**

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	AHHH	Nouri et al. (1990) "Selective and non-selective loss of immunoregulatory molecules (HLA-A,B,C antigens and LFA-3) in transitional cell carcinoma" J. Br. Cancer 62:603-606;
	AIII	Osband et al. (1990) "Problem in the investigational Study and Clinical Use of Cancer Immunotherapy" Immunology today 11(6): 193-195;
	AJJJ	Pepino et al. (1989) "Primate Cardiac Allo- and Xenotransplantation: Modulation of the Immune Response with Photochemotherapy" Eur. Surg. Res. 21:105-113;
	AKKK	Peterson and Seed (1987) "Monoclonal Antibody And Ligand Binding Sites of the T Cell Erythrocyte Receptor (CD2)" Nature 329:842-846;
	ALLL	Picker et al. (1990) "A Unique Phenotype of Skin-associated Lymphocytes in Humans" Am. J. Path. 136(5):1053-1068;
	AMMM	Poizot-Martin et al. (1991) "Are CD4 antibodies and peptide T new treatments for psoriasis" The Lancet 337:1477;
	ANNN	Prince (1989) "Requirement for both the CD3/T Cell Receptor Complex and the CD2/Lymphocyte Function-Associated Antigen-3 Adhesion System in Monocyte-Independent T Cell Activation By Oxidized Erythrocytes" Immunol. Investigations 18:1081-1093;
	AOOO	Prinz et al. (1991) "Chimaeric CD4 monoclonal antibody in treatment of generalised pustular psoriasis" The Lancet 338:320-321;
	APPP	Recny et al. (1990) "Structural and Functional Characterization of the CD2 Immunoadhesion Domain" J. Biol. Chem. 263:8542-8549;
	AQQQ	Rincon and Patarroyo (1989) "Effect of Antibodies From the T Cell (CD2' Only) and the NK/Non-Lineage (New Panel Only) Sections On Adhesion Of Jurkat (T) Cell to Human Erythrocytes" Tissue Antigens 33:285;
	ARRR	Sanders et al. (1988) "T Cell Adhesion Receptors LFA-1 And CD2 And Their Ligands ICAM-1 And LFA-3" Analysis in Adhesion, Cell Mediated Lysis, And As Markers Of T Cell Subsets" in The T-Cell Receptor, A.R. Liss, Inc., pp. 269-279;
	ASSS	Sayre et al. (1987), "Molecular cloning and expression of T11 cDNAs reveal a receptor-like structure on human T lymphocytes" Chemical Abstracts 107(15): Abstract 128218x;
	ATTT	Schopf (1986) "Stimulation of T Cells by Autologous Molecular Leukocytes and Epidermal Cells in Psoriasis" Arch. Dermatol. Res. 279:89-94;
	AUUU	Seed and Aruffo (1987) "Molecular Cloning of the CD2 Antigen, The T-Cell Erythrocyte Receptor, By A Rapid immunoselection procedure" Proc. Natl. Acad. Sci. USA 84:3365-3369
	AVVV	Selvaraj et al. (1987) "The T Lymphocyte Glycoprotein CD2 (LFA-2/T11/E-Rosette Receptor) Binds The Cell Surface Ligand LFA-3" FASEB J. 4(6):447 Abstract 760;
	AWWW	Sewell et al. (1986) "Molecular Cloning of the Human T-Lymphocyte Surface CD2 (T11) Antigen" Proc. Natl. Acad. Sci. USA 83:8717-8722;
	AXXX	Shaw et al. (1986) "Two Antigen-Independent Adhesion Pathways Used By Human Cytotoxic T-Cell Clones" Nature 323:262-264;
	AYYY	Simon et al. (1991) "Adhesion molecules CD11a, CD18, and ICAM-2 on Human Epidermal Langerhans Cells Serve a Functional Role in the Activation of Alloreactive T Cells" Soc. Invest. Dermat. 96: 148-151;
	AZZZ	Singer et al. (1990) "Thymocyte LFA-1 And Thymic Epithelial Cell ICAM-1 Molecules Mediate Binding of Activated Human Thymocytes to Thymic Epithelial Cells" J. Immunol. 144:2931-2939;
	AAAAA	Singer, K.H. et al. J. Invest. Dermatol. 94 (6) Supplement: 85S-90S

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Sheet 5 of 6

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**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Design ID	Document
	ABBBB	Smith and Thomas (1990) "Cellular Expression of Lymphocyte Function Associated Antigens and the Intercellular Adhesion Molecule-1 in Normal Tissue" J. Clin. Path. 45:893-900;
	ACCCC	Springer (1990) "Adhesion Receptors of the Immune System" Nature 346:425-434;
	ADDDD	Springer et al. (1987) "The Lymphocyte Function-Associated LFA-1, CD2, and LFA-3 Molecules: Cell Adhesion Receptors of the Immune System" Ann. Rev. Immunol. 5:223-252;
	AEEEE	Stauton et al. (1989) "Molecular characterization of ICAM-1 and ICAM-2; Alternate Ligands for LFA-1" Tissue Antigens 33:287;
	AFFFF	Stedman's Medical Dictionary, (1976) The Williams & Wilkins Company, Baltimore, MD, p. 810.
	AGGGG	Suranyi et al. (1991) "Lymphocyte Adhesion Molecules in T Cell-Mediated Lysis of Human Kidney Cells" Kidney International 39:312-319;
	AHHHH	Tadini (1989) "Adhesion Molecules Expression in Psoriasis" J. Invest. Dermatol. 93(2):309A;
	AIIII	Tang and Udey (1991) "Inhibition of Epidermal Langerhans Cell Function by Low Dose of Ultraviolet B Radiation" J. Immunol. 145:3347-3355;
	AJJJJ	Ullman et al. (1990) "Transmission of Signals from T Lymphocyte Antigen Receptor to the Genes Responsible for Cell Proliferation and Immune Function: The Missing Link" Ann. Rev. Immunol. 8:421-452;
	AKKKK	Valdimarsson et al. (1986) "Psoriasis: a disease of abnormal keratinocyte proliferation induced by T lymphocytes" Immunol. Today 7:256-259;
	ALLLL	van Sevrer et al. (1989) "The Three LFA-3 Specific Monoclonal Antibodies in the Non-Lineage panel of Workshop Monoclonal Antibodies All Inhibit T-Cell Rosetting" Tissue Antigens 33:298;
	AMMMM	Virella et al. (1988) "The Interaction of CD2 With Its LFA-3 Ligand Expressed By Autologous Erythrocytes Results in Enhancement of B Cell Responses" Cell. Immunol. 116:308-319;
	ANNNN	Vollger et al. (1987) "Thymocyte Binding to Human Thymic Epithelial Cells is Inhibited by Monoclonal Antibodies to CD-2 and LFA-3 Antigens," J. Immunol. 138:358-363
	AOOOO	Waldmann (1991) "Monoclonal Antibodies in Diagnosis and Therapy," Science 252:1657-1662
	APPPP	Walner et al. (1987) "Primary Structure of Lymphocyte Function-Associated Antigen 3 (LFA-3)-The Ligand of the Lymphocyte CD2 Glycoprotein" J. Exp. Med. 166:923-932;
	AQQQQ	Webb et al. (1990) "LFA-3, CD44, And CD45: Physiologic Triggers of Human Monocyte TNF and IL-1 Release" Science 249:1295-1297;
	ARRRR	Winter and Harris (1993) "Humanized antibodies" TIPS 14:139-142;
	ASSSS	Yong and Khwaja (1990) "Leukocyte Cellular Adhesion Molecules" Blood Reviews 4:211-225;
	ATTTT	Zheng et al. (1990) "Expression of Intercellular and Adhesion Molecule-1 and Lymphocyte Function-Associated Antigen-3 on Human Thyroid Epithelial Cells in Graves' and Hashimoto's Diseases" J. Autoimmunity 3:727-736;
	AUUUU	
	AVVVV	Chisholm et al. (1994) "The effects of an immunodulatory LFA3-IgG <sub>1</sub> fusion protein on nonhuman primates," Therapeutic Immunology 1: 205-216.
	AWWWW	Ding et al. (1996) "A novel murine model for the assessment of human CD2-related reagents <i>In Vivo</i> ," J. Immunol. 157(5): 1863-1869.

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	AXXXX	Gamache et al. (1996) "Pharmacokinetics of LFA3TIP, an immunoglobulin fusion protein, in male and female baboons," <i>Pharmaceutical Research</i> 13 (9 Sup.): s399.
	AYYYY	Kaplon et al. (1996) "Short course single agent therapy with an LFA-3-IgG <sub>1</sub> fusion protein prolongs primate cardiac allograft survival." <i>Translation</i> 61(3): 356-363.
	AZZZZ	Majeau et al. (1994), "Mechanism of lymphocyte function-associated molecule 3-Ig fusion proteins inhibition of T cell responses," <i>J. of Immunol.</i> 2753-2767.
	AAAAAA	Meier et al (1995) "Immunomodulation by LFA3TIP, an LFA-3/IgG <sub>1</sub> fusion protein: cell line dependent glycosylation effects on pharmacokinetics and pharmacodynamic markers," <i>Therapeutic Immunology</i> 2: 159-171.
	ABBBBB	Miller et al. (1993) "Specific interaction of lymphocyte function associated antigen 3 with CD2 can inhibit T cell responses," <i>J. Exp. Med.</i> 178: 211-222.
	ACCCCC	Moingeon et al. (1989), "CD2-mediated adhesion facilitates T lymphocyte antigen recognition function," <i>Nature</i> 339: 312-339.
	ADDDDD	Osborn et al. (1995), "Amino acid residues required for binding of lymphocyte function-associated antigen 3 (CD58) to its counter-receptor CD2," <i>J. Exp. Med.</i> 181(1): 429-434.
	AEEEEEE	Pepinsky et al. (1991), "The increased potency of cross-linked lymphocyte function-associated antigen-3 (LFA-3) multimers is a direct consequence of changes in valency," <i>J. Biol. Chem.</i> 266(27): 18244-18249.
	AFFFFF	Riggs et al. (1996), "The pharmacokinetic/pharmacodynamic (PK/PD) modeling of immunoglobulin fusion protein, LFA3TIP, using a non-linear saturable cell activity model," <i>Pharmaceutical Research</i> 13 (9 Supp.): s398.
	AGGGGG	Savage et al. (1991), "Endothelial cell lymphocyte function-associated antigen-3 and an unidentified ligand act in concert to provide costimulation to human peripheral blood CD4 <sup>+</sup> T cells," <i>Cellular Immunology</i> 137: 150-163.
	AHHHHH	Semnani et al. (1994), "Costimulation by purified intercellular adhesion molecule 1 and lymphocyte function-associated antigen 3 induces distinct proliferation, cytokine and cell surface antigen profiles in human "naïve" and "memory" CD4 <sup>+</sup> T cells," <i>J. Exp. Med.</i> 180: 2125-2135.
	AIIIII	Wallner et al. (1987), "Primary structure of lymphocyte function-associated antigen 3 (LFA-3): The ligand of the T lymphocyte CD2 glycoprotein," <i>J. Exp. Med.</i> 166: 623-932.

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